

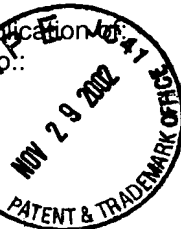
ASSISTANT COMMISSIONER FOR PATENTS  
Washington, DC 20231In re application of:  
Serial No.:  
Filed:  
For:  
Sir:

Ronald M. BURCH, et al.

10/056,347

January 25, 2002

ANALGESIC COMBINATION OF OXYCODONE AND MELOXICAM



TECH CENTER 1600/2900

DEC 04 2002

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Transmitted herewith is a **Preliminary Amendment** in the above-identified application.

- ☐ Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.  
☐ Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.  
☒ No fee for additional claims is required.  
☐ A filing fee for additional claims calculated as shown below, is required:

FOR:	(Col. 1)	(Col. 2)		SMALL ENTITY		OR	LARGE ENTITY	
	REMAINING	HIGHEST		RATE	FEE		RATE	FEE
	AFTER	PREVIOUSLY	PRESENT					
	AMENDMENT	PAID FOR	EXTRA					
TOTAL CLAIMS	* Minus**	=		x \$ 9	\$		x \$ 18	\$
INDEP. CLAIMS	* Minus***	=		x \$ 42	\$		x \$ 84	\$
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				+ \$140	\$		+ \$280	\$

TOTAL: \$ OR TOTAL: \$

- \* If the entry in Co. 1 is less than the entry in Col. 2, write "0" in Col. 3.  
 \*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.  
 \*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

☒ Also transmitted herewith are:

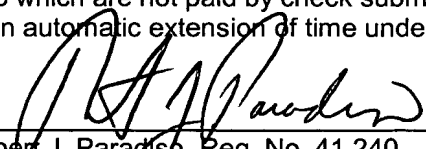
- ☐ Petition for extension under 37 C.F.R. 1.136 (in duplicate)  
☒ Other: **Information Disclosure Statement (3 pages)**  
**Form PTO-1449 (3 pages)**  
**Exhibit A (15 pages)**

☐ Check(s) in the amount of \$.00 is/are attached to cover:

- ☐ Filing fee for additional claims under 37 C.F.R. 1.16  
☐ Petition fee for extension under 37 C.F.R. 1.136  
☐ Other:

☒ The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.

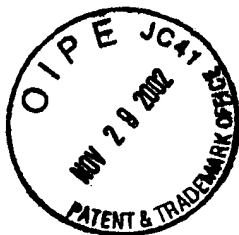
- ☒ Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.  
☒ Any patent application processing fees under 37 C.F.R. 1.17.  
☒ Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

  
 Robert J. Paradiso, Reg. No. 41,240  
 DAVIDSON, DAVIDSON & KAPPEL, LLC  
 485 Seventh Avenue, 14<sup>th</sup> Floor  
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 Tel: (212) 736-1940  
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I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on November 22, 2002.

DAVIDSON, DAVIDSON &amp; KAPPEL, LLC

BY: 



200.1079CON2

CF  
12/16/02

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Examiner: Not Yet Known      Art Unit: 1627  
Re:    Application of:      Ronald M. BURCH, et al.  
      Serial No.:      10/056,347  
      Filed:      January 25, 2002  
      For:      **ANALGESIC COMBINATION OF  
                  OXYCODONE AND MELOXICAM**

**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

November 22, 2002

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97(b), Applicants hereby make of record the references listed on the accompanying Form PTO-1449 (3 pages ) and the following copies of Information Disclosure Statements (15 pages) submitted during the prosecution of the parent application U.S. Serial No. 09/154,354. The following are enclosed as Exhibit A:

- Information Disclosure Statement of June 7, 1999 (2 pages);
- Information Disclosure Statement of June 7, 1999 (2 pages);
- Information Disclosure Statement of June 7, 1999 (2 pages);
- Information Disclosure Statement of February 4, 2000 (2 pages);
- Information Disclosure Statement of September 26, 2001 (2 pages);
- Information Disclosure Statement of September 13, 2002 (3 pages); and
- Information Disclosure Statement of October 1, 2002 (2 pages).

It is noted that the Information Disclosure Statement of September 13, 2002, refers to Appendix A, which is a Statement of Grounds and Particulars in Support of Opposition dated June 14, 2002, brought by Pharmacia Corporation at the Australian Patent Office opposing Australian Patent Application No. 742097 (93984/98), the corresponding Australian application of the parent U.S. application (Serial No. 09/154,354), and Appendix B, which is a copy of the current claims of Australian Patent Application No. 742097 (93984/98) which claims the same priority as the present application. In addition, Information Disclosure Statement of October 1, 2002, refers to Appendix A, an amendment of the Statement of Grounds and Particulars in Support of Opposition dated August 14, 2002. Specifically, Appendix A lists a further document (referenced in the Statement as D38) in addition to the references listed in Appendix A of the Information Disclosure Statement filed on September 13, 2002. Furthermore, reference D38 corresponds to reference AH in the Form PTO-1449 submitted on October 1, 2002.. These Appendices and attachments are not enclosed as these documents have already been made of record in the parent application.

Applicants respectfully point out to the Examiner that the PTO-1449 forms accompanying this Information Disclosure Statement list the references cited in Opposition to the corresponding Australian Patent Application No. 742097 (93984/98) of the parent U.S. Application (Serial No. 09/154,354. Copies of these references were submitted in the parent case (Serial No. 09/154,354) along with the above-referenced Information Disclosure Statements of September 13, 2002 (references AA through BM of Form PTO-1449) and October 1, 2002 (reference AH of page 1 of 1 of Form PTO-1449). Accordingly, pursuant to 37 CFR § 1.98(d), copies of the references listed on the accompanying Form PTO-1449 are not enclosed as these references have already been made of record. If it is determined that any of the listed references are not of record, the Examiner is requested to contact the undersigned so that a copy can be promptly forwarded.

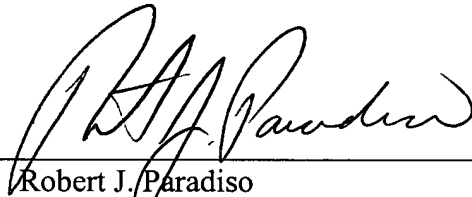
This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) before the mailing date of a First Office Action on the merits. Therefore, no fee is believed to be due for filing this Information Disclosure Statement. If it is determined that any fees are due, the Assistant Commissioner is hereby authorized to charge said fees to Deposit Account No. 50-0552.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered by the Examiner and made of record. If any of the listed references are found to be missing, the Examiner is requested to contact the undersigned so that a copy may be promptly forwarded.

Respectfully Submitted,

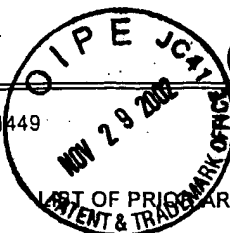
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: \_\_\_\_\_



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PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
200.1079US

SERIAL NO.: 09/154,354

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Ronald M. BURCH, et al.

FILING DATE:  
September 17, 1998

GROUP: 1627

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AA	0	6	5	4	2	6	3	05/24/95	EP (A1)	A61K	31/135		
	AB	0	6	5	4	2	6	3	05/24/95	EP (B1)	A61K	31/135		
	AC	9	7	1	7	9	7	8	05/22/97	WO	A61K	33/00		
	AD	9	7	2	5	9	8	8	07/24/97	WO	A61K	31/495		
	AE	9	7	3	2	8	5	7	09/12/97	WO	C07D	241/104		

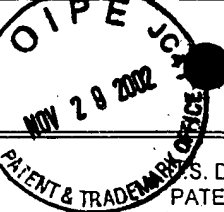
## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AF	Dray et al. New Pharmacological Strategies for Pain Relief. <u>Annual Review of Pharmacology &amp; Toxicology</u> , 36, pp. 253-280. (1996).
AG	Brasseur. L. Revue des therapeutiques pharmacologiques actuelles de la douleur. <u>Drugs</u> , 53 Suppl 2, pp. 10-17. (1997)
AH	Rang et al. New molecules in analgesia. <u>British Journal of Anesthesia</u> , 75, pp. 145-156 (1995)
AI	Beaver, WT. Combination Analgesics. <u>American Journal of Medicine</u> , 77 (Suppl 3A), pp. 38-53. (1984).
AJ	Beaver, WT. Chapter 29: Nonsteroidal Antiinflammatory Analgesics and Their Combinations with Opioids. In <u>Evaluation and Treatment of Chronic Pain</u> , 2 <sup>nd</sup> ed., William & Wilkins pp. 363-383. (1992).
AK	Goodman & Gilman's. The Pharmacological Basis of Therapeutics, 9 <sup>th</sup> Edition. McGraw-Hill, New York, pp 535 and 551-552.
AL	Picard et al. Ketorolac potentiates morphine in postoperative patient-controlled analgesia. <u>Pain</u> , 73, 3 pp. 401-406. (1997).
AM	Etches et al. Continuous Intravenous Administration of Ketorolac Reduces Pain and Morphine Consumption After Total Hip or Knee Arthroplasty. <u>Anesthesia &amp; Analgesia</u> , 81 (6), pp. 1175-1180. (1995).
AN	Hoddsman et al. The morphine sparing effects of diclofenac sodium following abdominal surgery. <u>Anaesthesia</u> , 42(9), pp. 1005-1008. (1987).
AO	Kaasalainen et al. Developments in the treatment of cancer pain in Finland: The third nation-wide survey. <u>Pain</u> , 70, 2-3, pp. 175-183. (1997).
AP	Sunshine et al. Analgesic Efficacy of a Hydrocodone with Ibuprofen Combination Compared with Ibuprofen Alone for the Treatment of Acute Postoperative Pain. <u>Journal of Clinical Pharmacology</u> , 37 (10), pp. 908-915. (1997).
AQ	Insel. Chapter 27: Analgesic-Antipyretic and Anti-inflammatory Agents. In Hardman, ed., <u>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</u> , 9 <sup>th</sup> Edition. McGraw-Hill, New York, pp. 654-655. (1996).
AR	Polisson. Non-steroidal Anti-inflammatory Drugs: Practical and Theoretical Consideration in Their Selection. <u>The American Journal of Medicine</u> , 100 (Suppl 2A), pp. 2A-31S - 2A-36S. (1996).
AS	Vane, J. Towards a better aspirin. <u>Nature</u> , 367, pp. 215-216. (1994).
AT	Simon, L.S. Nonsteroidal Antiinflammatory Drugs and Their Effects: The Importance of COX 'Selectivity'. <u>Journal of Clinical Rheumatology</u> , 2 (3), pp. 135-140. (1996).

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
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SERIAL NO.: 09/154,354

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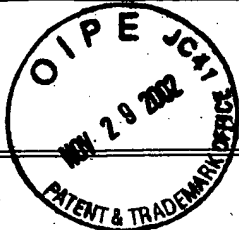
## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

BA	Van Ryn et al. Selective cyclooxygenase-2 inhibitors: pharmacology, clinical effects, and therapeutic potential. <u>Expert Opinion On Investigational Drugs</u> , pp. 609-614. (1997).
BB	Vane et al. New insights into the mode of action of anti-inflammatory drugs. <u>Inflammation Research</u> , 44, (No.1), pp 1-10 (1995).
BC	Engelhardt. Meloxicam: A Preferential Inhibitor of COX-2. <u>British Journal of Rheumatology</u> , 34, Abstract Suppl. 1, p. 48. (1995). Abstract.
BD	Lane, N.E. Pain Management in Osteoarthritis: The Role of COX-2 Inhibitors. <u>Journal of Rheumatology</u> , Vol. 24, Suppl 49, pp. 20-24. (1997).
BE	Boyce et al. L-745,337: A Selective Inhibitor of Cyclooxygenase-2 Elicits Antinociception But Not Gastric Ulceration in Rats. <u>Neuropharmacology</u> Vol. 33, pp. 1609-1611. (1994).
BF	Donnelly et al. COX-II Inhibitors - a new generation of safer NSAIDS? <u>Alimentary Pharmacology and Therapeutics</u> , 11, 2, pp. 227-236. (1997).
BG	Wallace, J.L. Nonsteroidal Anti-inflammatory Drugs and Gastroenteropathy: The Second Hundred Years. <u>Gastroenterology</u> , 112, 3, pp. 1000-1016. (1997).
BH	Robinson, D.R. Regulation of Prostaglandin Synthesis by Antiinflammatory Drugs. <u>J Rheumatology</u> , 24, Suppl. 47, pp. 32-39. (1997).
BI	Tannenbaum et al. An Evidence-Based Approach to Prescribing NSAIDS in Musculoskeletal Disease: A Canadian Consensus. <u>Canadian Medical Association Journal</u> , 155, 1, pp. 77-88. (1996).
BJ	Mehlsch et al. Analgesic Efficacy and Plasma Levels of a Highly Selective Inhibitor of COX-2 (SC-58635, SC) in Patients with Postsurgical Dental Pain. <u>Journal of Clinical Pharmacology</u> , 37, 9, 863. (1997). Abstract.
BK	Dammann. Selective COX-2 Inhibition: Its Relevance for NSAID-Gastrointestinal Toxicity. <u>Gut</u> , 39, Suppl. 3, A151. (1996). Abstract.
BL	Penning et al. Synthesis and Biological Evaluation of the 1, 5-diarylpyrazole class of cyclooxygenase-2 inhibitors: Identification of 4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide (SC-58635, Celecoxib). <u>Journal Of Medicinal Chemistry</u> , 40(9), 1347-65. (1997).
BM	Lipsky et al. Outcome of Specific COX-2 Inhibition in Rheumatoid Arthritis. <u>Journal Of Rheumatology</u> , 24 Suppl 49, pp. 9-14. (1997).
BN	
BO	
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	AC						
	AD						
	AE						
	AF						
	AG						

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	AH	0 7 3 4 2 7 5	11/04/1997	Australia	C07D	261/08		
	AI							
	AJ							
	AK							
	AL							

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